NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHIRE LLC et al., Plaintiffs, v. AMNEAL PHARMACEUTICALS, LLC et al., Defendants.	:	Civil Action No. 11-3781 (SRC) **OPINION & ORDER**

SHIRE LLC et al., Plaintiffs, v. WATSON LABORATORIES, INC. et al., Defendants.	:	Civil Action No. 12-83 (SRC)

CHESLER, District Judge

This matter comes before the Court on the applications by Plaintiffs Shire LLC, Shire Development Inc. and Shire Development LLC (collectively, "Plaintiffs"), and Defendants Amneal Pharmaceuticals, LLC, Actavis Elizabeth LLC, Sandoz Inc., Roxane Laboratories, Inc., Watson Laboratories Inc., Mylan Pharmaceuticals Inc., Mylan Inc., Johnson Matthey Inc. and Johnson Matthey Pharmaceutical Materials (collectively, "Defendants"), for claim construction to resolve disputes over the construction of claim terms in eighteen patents. The Court held oral argument on August 5, 2013. For the reasons stated below, the Court in part adopts Plaintiffs'

proposed constructions, in part adopts Defendants' proposed constructions, and in part adopts neither.

BACKGROUND

This matter involves two Hatch-Waxman actions for patent infringement. The cases both deal with patents owned by Plaintiffs which relate to certain amphetamine compounds and treatment methods, including L-lysine-d-amphetamine ("LDX") and lisdexamfetamine dimesylate, marketed as the drug Vyvanse®. The moving Defendants are generic pharmaceutical manufacturers who have filed Abbreviated New Drug Applications seeking FDA approval to engage in the manufacture and sale of generic versions of Vyvanse® prior to the expiration of Plaintiffs' patents, and their suppliers.

In Civil Action No. 12-83, the generic manufacturer has been dismissed from the case, leaving only suppliers Johnson Matthey Inc. and Johnson Matthey Pharmaceutical Materials as Defendants. While Plaintiffs have applied for claim construction in this case, Johnson Matthey Inc. and Johnson Matthey Pharmaceutical Materials have not opposed Plaintiffs' application in Civil Action No. 12-83.

The Defendants who have opposed Plaintiffs' application for claim construction do so solely in Civil Action No. 11-3781. In that action, eighteen patents are at issue:

U.S. Patent No. 7,105,486 (the "'486 patent");

U.S. Patent No. 7,223,735 (the "'735 patent");

U.S. Patent No. 7,655,630 (the "' 630 patent");

U.S. Patent No. 7,659,253 (the "'253 patent");

U.S. Patent No. 7,659,254 (the "'254 patent");

U.S. Patent No. 7,662,787 (the "'787 patent");

U.S. Patent No. 7,662,788 (the "'788 patent");

U.S. Patent No. 7,671,030 (the "'030 patent");

U.S. Patent No. 7,671,031 (the "'031 patent");

U.S. Patent No. 7,674,774 (the "'774 patent");

U.S. Patent No. 7,678,770 (the "'770 patent");

U.S. Patent No. 7,678,771 (the "'771 patent");

U.S. Patent No. 7,687,466 (the "'466 patent");

U.S. Patent No. 7,687,467 (the "'467 patent");

U.S. Patent No. 7,713,936 (the "'936 patent");

U.S. Patent No. 7,718,619 (the "'619 patent");

U.S. Patent No. 7,723,305 (the "'305 patent"); and

U.S. Patent No. 7,700,561 (the "'561 patent").

After the completion of briefing, the parties filed cross-motions to strike parts of each others' materials, which were granted in part and denied in part. The parties resubmitted their applications for claim construction in accordance with that decision.

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). The Court decides claim construction as a matter of law: "the

construction of a patent, including terms of art within its claim, is exclusively within the province of the court." Markman v. Westview Instruments, 517 U.S. 370, 372 (1996).

> The focus of claim construction is the claim language itself:
> It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.
> The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
>
> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed terms

A. Terms 76, 76a, 78 and 79:[1] "L-lysine-d-amphetamine"

Terms 76, 76a, 78 and 79 concern references to "L-lysine-d-amphetamine" (LDX). Although terms 76 and 76a refer to the dimesylate salt of LDX, and term 78 refers to the mesylate salt of LDX, the claim construction dispute here concerns the common element in terms 76, 76a, 78 and 79, which is "L-lysine-d-amphetamine." This phrase appears throughout the claims of the 18 patents in suit.

Plaintiffs first contend that Defendants' arguments about this term in their briefs are not moored to their proposed construction in the Joint Statement. Although this Court does not here resolve this claim construction dispute on this basis, it counsels parties not to advance claim constructions for which they have failed to provide notice in the Joint Statement required by L. Pat. Rule 4.3. Certainly, if there is a connection between Defendants' proposed construction in the Joint Statement and the arguments in their briefs, they have not pointed it out, nor is it obvious to this Court. But, as stated, this does not provide the basis for this Court's claim construction decision.

The dispute, as briefed, rests on the question of whether LDX, when used as a claim term, encompasses both protected and unprotected forms, as Defendants contend, or only the

[1] The two sides in this dispute have used different numbering schemes for the claim terms at issue. For simplicity, in this Opinion, the Court has used Plaintiffs' numbering.

unprotected form, as Plaintiffs contend.[2] It does not appear that there is any actual dispute about what LDX is chemically. Rather, this dispute arises from Defendants' theory that the patentees' use of the words "protected" and "unprotected" has somehow redefined this term. As Plaintiffs observe, LDX is not a genus; it is a species. Defendants point to no definition anywhere in the patent files which defines LDX as a genus, with protected and unprotected forms as species within that genus. Nor do Defendants offer any expert opinion stating that LDX is a genus.

Defendants argue, incorrectly, that Plaintiffs seek to restrict the meaning of LDX to unprotected forms on a theory akin to prosecution disclaimer. This is incorrect. Plaintiffs contend that the applicants, acting as lexicographers, understood LDX to mean LDX in its unprotected form. Plaintiffs do not advance any disclaimer theory.

Defendants also accuse Plaintiffs of improperly importing limitations from the specification, contrary to the guidance of Phillips. The section of Phillips that Defendants cite, however, warns against limiting a claim term based an a particular embodiment in the specification. 415 F.3d at 1323. Plaintiffs have not advocated doing so. Rather, they argue in favor of applying an express definition in the specification to the claims, which is entirely different and not contrary to the guidance of the Federal Circuit in Phillips.

Plaintiffs point out that the patentees expressly defined LDX in the specification of the '253 patent as follows:

> The following abbreviations are used in the Examples and throughout the specification: Lys-Amp=L-lysine-d-amphetamine, Lysine-Amphetamine, K-Amp, K-amphetamine, or 2,6-diaminohexanoic acid-(1-methyl-2-phenylethyl)-amide,

---

[2] The parties neither define nor dispute what protected and unprotected forms are, but they appear to involve the presence or absence of a small chemical modification to a compound of interest.

lisdexamphetamine or Lisdexamfetamine . . .

'253 patent, col.30 ll.12-17. Plaintiffs also point to a diagram of the chemical structure offered by the applicants in the June 23, 2009 amendment to application no. 11/400,304, which defines LDX by a chemical diagram. (Plaintiffs' Ex. 34 at SHRVYV0032458-59.)

Defendants point to nothing in these definitions, nor in any definition in the intrinsic evidence, that defines LDX as a genus. The specification "acts as a dictionary when it expressly defines terms used in the claims." Phillips, 415 F.3d at 1321. LDX is thus a specific compound, 2,6-diaminohexanoic acid-(1-methyl-2-phenylethyl)-amide. Defendants have shown no basis to construe this as defining a genus with protected and unprotected forms. As a claim term, LDX is that particular chemical, and only that.

The specification sections of all the patents support this construction. As Plaintiffs explain – and Defendants do not refute – the protected/unprotected distinction is relevant to the synthesis of LDX, not to the finished product referred to in the claims. Some methods for synthesis have an intermediate step in which the lysine component is modified with a molecule that is said to "protect" it, i.e., to maintain its integrity during the synthesis process. Before the end of the synthesis process, that modification is removed in a process termed "deprotection." For example, the specification of the '253 patent contains this subsection:

> Synthesis of Lisdexamphetamine and Salts Thereof
>
> Lisdexamphetamine and salts thereof can be prepared from L-lysine or a salt thereof as follows. The amine groups on the L-lysine or a salt thereof are protected, for example, by reaction with di-tert-butyl dicarbonate. . .
>
> The di-amine protected L-lysine is then subjected to an acid activation followed by an amidation reaction with d-amphetamine to form a di-amine protected lisdexamphetamine. The amidation reaction can be performed either by first

> activating the acid group of the protected L-lysine, and then amidating the activated acid by, for example, reacting it with d-amphetamine ("two-step procedure"), or in a "one-pot procedure" in which the protected L-lysine, d-amphetamine, coupling reagent, and optional additive are all combined simultaneously. . .
>
> The di-amine protected lisdexamphetamine is then deprotected and optionally converted to a salt. The deprotection and salt conversion can be performed in a single reaction. For example, the di-amine protected lisdexamphetamine can be reacted with methane sulfonic acid to form lisdexamphetamine dimesylate.

'253 patent, col.13 l.55-col.14 l.49. In this method, one ingredient, l-lysine, is protected at an intermediate step, and reacted to produce a di-amine protected lisdexamphetamine. Then, the di-amine protected lisdexamphetamine is reacted to remove the protecting molecule, resulting in an unprotected final product – in this example, the LDX dimesylate salt.

Curiously, Defendants point to this very section in support of their position, contending that the use of the phrase "protected lisdexamphetamine" shows that LDX may be in either a protected or unprotected form. This is unpersuasive for two reasons. First, the meaning of this section is very clear: the intermediate has been protected and the final product has been deprotected. Second, the fact that the patentees used the phrase "di-amine protected lisdexamphetamine" is consistent with the understanding that lisdexamphetamine, standing alone and without an accompanying modifier, is the unprotected form.

Defendants observe that each one of the 18 patents at issue has the same "Example 2," which discloses a method for the synthesis of LDX. See, e.g., '735 patent, col.20 l.35-col.21 l.28. As Defendants correctly observe, Example 2 begins with the synthesis of a "purified protected amide." '735 patent, col.20 l.62. The problem for Defendants is that Example 2 does not stop there: this stage is followed by a "deprotection" stage, which produces the final product,

LDX. '735 patent, col.21 l.3. This is consistent with the understanding that the protected form is an intermediate step in the synthesis process, and that the unprotected form is the final product, LDX.

Defendants' arguments for understanding LDX as a claim term to be a genus are unpersuasive. Defendants begin by pointing to claim 1 of the '735 patent: "A pharmaceutical composition comprising an unprotected prodrug and one or more pharmaceutically acceptable additives; wherein said prodrug consists of L-lysine-d-amphetamine or a pharmaceutically acceptable salt thereof. . ." Defendants contend that this shows that the patentees knew how to use words to limit the scope of LDX to an unprotected form, and so, when LDX is not so limited, it must encompass both protected and unprotected forms. As Plaintiffs point out, the problem with this argument is that "unprotected" in claim 1 modifies "prodrug," not LDX.[3] This example could support the proposition that "prodrug" is a genus, but it does not show that the patentees felt a need to limit the scope of the LDX term.

Defendants' last arguments in their opening brief are that Plaintiffs' construction: 1) improperly renders superfluous the claim term "unprotected" in other claims; and 2) impermissibly excludes embodiments disclosed in the specifications. Defendants do not cite from any of the patents to support these assertions. The first argument appears to refer to claim 1 of the '735 patent, just discussed. Plaintiffs' construction does not render the claim term "unprotected," which modifies "prodrug," superfluous. As to the second point, Defendants have not pointed out any example in any patent in which the final product was protected. As a result,

[3] It is also worth noting that claim 1 of the '735 patent claims the unprotected form, which is consistent with Plaintiffs' construction. Defendants do not point to any claim in any of the patents which claims a protected form.

this Court does not agree that Plaintiffs' construction excludes embodiments cited in the specification.

Defendants make additional points in their responsive brief. Defendants point to the use of the word "isolated" in claims 1 and 2 of the '787 patent, contending that somehow, read in connection with Example 2, this supports their case; this is unclear. Defendants next state: "All patents-in-suit disclose L-lysine-d-amphetamine in 'a free and unprotected state.'" (Defs.' Resp. Br. 7.) The brief then cites to 3 patents, including this sentence in the '735 patent: "A further embodiment of the carrier and/or conjugate is that the unattached portion of the carrier/conjugate may be in a free and unprotected state, or in the form of an ester or salt thereof." '735 patent, col.3 l.66-col.4 l.2. This is not worth lengthy discussion, but Defendants appear to have misunderstood that sentence. The context for this statement is a discussion of the genus of compounds formed by the attachment of amphetamines to carrier peptides. '735 patent, col.3 ll.40-55. The sentence in question does not refer to LDX, nor to an amphetamine precursor of LDX, but to embodiments of the carrier molecule which is attached to the amphetamine.

Plaintiffs' responsive brief bolsters their position with two points. First, in its notice letter to Plaintiffs, Defendant Mylan defined LDX in the same way that Plaintiffs have proposed. (Fleming Dec. Ex. 63 at SHRVYV0417916.) Second, Plaintiffs point to a particular submission from the applicants to the Examiner (Fleming Dec. Ex. 34 at SHRVYV0032462), but there is another similar submission that makes Plaintiffs' point even better. In the submission filed October 10, 2006 pertaining to application no. 10/857,619, the applicants state:

> Contrary to the statement at page 5 of the Official Action, applicants urge that NL 6414901 does not expressly teach L-lysine-d-amphetamine at page 11, compound 9. As the examiner acknowledges, it is the compound further including the tosyl

> protecting group which is what the NL patent discloses. Implicit in the Examiner's rejection is the notion that the L-lysine-d-amphetamine was the desired final product, whereby the only thing standing between such final product and the protected intermediate was the routine removal of a well-known protecting group.

(Fleming Dec. Ex. 34 at SHRVYV0004237.) In this excerpt, the applicants correct the Examiner, who appears to have referred to a compound with a tosyl protecting group as L-lysine-d-amphetamine. The applicants point out that such a compound is not L-lysine-d-amphetamine. This makes clear that the applicants did not consider a compound composed of L-lysine-d-amphetamine and a tosyl protecting group to be L-lysine-d-amphetamine. Moreover, the applicants proceed to refer to this compound as "tosylated L-lysine-d-amphetamine." (Fleming Dec. Ex. 34 at SHRVYV0004238.) This strongly supports Plaintiffs' position.

The Court concludes that Plaintiffs' construction of "L-lysine-d-amphetamine" is the correct one, and that this claim term does not include protected forms.

In their opening brief, Plaintiffs also argue that, as to term 76a, the dimesylate salt of LDX may have a water content. Defendants do not address this issue. Defendants have not opposed Plaintiffs' position, and so the phrase "L-lysine-d-amphetamine dimesylate" is construed to mean "L-lysine-d-amphetamine dimesylate (that may have a water content)."

B. Term 130: "X-ray powder diffraction pattern substantially as shown in FIG. 77"

Claim 2 of the '253 patent states: " The crystalline lisdexamphetamine dimesylate of claim 1, wherein the crystalline lisdexamphetamine dimesylate exhibits an X-ray powder diffraction pattern substantially as shown in FIG. 77." Although the parties have asked for construction of the term "substantially," Plaintiffs propose a construction which includes the word "substantially," and references Table 73. Defendants propose a construction that attempts

to draw numerical boundaries around "substantially," in the context of Figure 77. The Court held oral argument on August 5, 2013 and asked the parties to explain how the intrinsic evidence gives meaning to their proposed constructions of "substantially." Neither party has persuaded this Court that their proposed construction is correct.

The patent does not speak clearly to the subject of the comparison of X-ray powder diffraction ("XRPD") patterns. At most, it gives some slight hints. One such hint is Table 73. In example 40, the specification states:

> The XRPD spectra of a sample of the crystalline L-lysine-d-amphetamine dimesylate prepared according to example 39 is shown in FIG. 77. Peak locations (in degrees 2θ±0.2, 0.1, 0.05, or 0.01° C.) for the XRPD pattern in FIG. 77 are provided in table 73, below.

'253 patent, col.84 ll.17-21. As Defendants pointed out at oral argument, the data in Table 73 represents only part of Figure 77: it omits the part of the graph at values of 30 2θ and above. As Defendants also pointed out, the figures in Table 73 in the "Intensity" column are transformations of the intensity values in Figure 77. Table 73 thus does not fully quantify Figure 77, nor does it elucidate the meaning of the claim term "substantially."

Defendants propose a construction that converts "substantially" into clear numerical boundaries. Yet the intrinsic evidence suggests that this is not what the patentees had in mind. As Defendants themselves pointed out at the hearing, claims 3 through 5 use numerical limits to set the boundary around specific XRPD patterns. For example, claim 3 states: "The crystalline lisdexamphetamine dimesylate of claim 1, wherein the crystalline lisdexamphetamine dimesylate exhibits an X-ray powder diffraction pattern having at least one peak in degrees 2θ±0.2 2θ selected from 4.5, 9.0, 12.0, 15.7, and 16.3." Claim 3 thus sets a precise numerical boundary

around a specific XRPD pattern. This tells us that the patentees knew how to precisely delineate the bounds of XRPD patterns, and chose not to do so in claim 2.

On this issue, this Court is guided by the Federal Circuit's recent decision in Aventis Pharms., Inc. v. Amino Chems. Ltd., 715 F.3d 1363, 1377 (Fed. Cir. 2013). At issue in that case was the construction of the phrase, "substantially pure." Id. The Federal Circuit first examined the intrinsic evidence, but found that it did not shed light on the meaning of "substantially." Id. The Court stated:

> With no explicit construction of the term 'substantially pure' in the claims, specification, or prosecution history, we apply the 'ordinary and customary' definition to the claim term. In other contexts, this court has interpreted 'substantially' as a non-specific term of approximation that avoids a numerical boundary. *See, e.g., Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 907 (Fed. Cir. 2005); *Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361, 1368 (Fed. Cir. 2004) ("The term 'substantial' is a meaningful modifier implying 'approximate,' rather than 'perfect.'").

Id. Similarly, in the instant case, this Court finds no explicit construction of the term "substantially" in the claims, specification, or prosecution history of the '253 patent, and so it applies the ordinary and customary definition to the claim term. The intrinsic evidence indicates that "substantially" is a non-specific term of approximation that avoids a numerical boundary. The phrase "X-ray powder diffraction pattern substantially as shown in FIG. 77" is construed to mean "X-ray powder diffraction pattern approximately as shown in FIG. 77."[4]

C. Term 28: "amphetamine"

Plaintiffs contend that "amphetamine" has one definition in four patents, but means

[4] At the hearing, Plaintiffs' counsel expressed the concern that, were "substantially" here construed to mean "about," it would implicate the patent's express definition of "about." The present construction of "substantially" does not implicate the patent's express definition of "about." '253 patent, col.11 ll.52-58.

something else in a fifth patent: it means "d-amphetamine" in the claims in the '486, '735, '031, and '561 patents, but has a more general meaning in the context of the claims in the '788 patent. Defendants contend that "amphetamine" is expressly defined in the specification in the '735 and '486 patents,[5] and that the '031 and '561 patents incorporate by reference the '735 and '486 patents. The parties appear to essentially agree that "amphetamine" has a broader meaning in the context of the claims in the '788 patent.[6]

As for the four patents in which Plaintiffs contend that "amphetamine" as a claim term means "d-amphetamine" specifically, the problem for Plaintiffs is that, given an express definition of the term in two of the four patents, and the incorporation by reference of these express definitions in the two others, they have not given a persuasive reason for this Court to ignore and override the patentees' express definitions. Plaintiffs point to the clear problem in meaning posed by the express definition in the patents: it is circular – it uses "amphetamine" to define "amphetamine." This cannot be disputed. This Court infers from this that the patentees used "amphetamine" in two senses, a broader sense and a narrower one. Yet Plaintiffs then argue from this that this Court should adopt an even narrower construction than is in the express definition! This does not make sense.

In claim construction, the Federal Circuit gives claim language the broadest reasonable construction, in light of the specification. Phillips, 415 F.3d at 1316. Given that the patentees

---

[5] "'Amphetamine' shall mean any of the sympathomimetic phenethylamine derivatives which have central nervous system stimulant activity, such as but not limited to, amphetamine, methamphetamine, . . ." '735 patent, col.9 ll.61-64.

[6] The parties propose slightly different wordings for their constructions, the principal difference being that Plaintiffs add at the end "or any derivative, analog, or salt thereof." Neither party has suggested that the differences in wording make for any material difference in meaning.

appeared to use "amphetamine" in both broader and narrower ways, the broadest reasonable construction is, necessarily, the broader of the two. Thus, the broader definition of "amphetamine" controls the interpretation of the words in the claims. There is no other reasonable way to understand this. Certainly, there is nothing in the express definition to suggest that "amphetamine" as a claim term should be limited to "d-amphetamine."

Plaintiffs' opening brief only cites two pieces of intrinsic evidence to support their proposed limitation. First, they point to a chemical diagram in the '735 patent (col.10 ll.1-11) which, in the absence of any explanation, does not speak to the Court. Second, they point to this statement in the specification of the '031 patent: "The amphetamine can have any stereogenic configuration, including both dextro- and levo-isomers. The dextro-isomer, particularly dextroamphetamine, is preferred." '031 patent, col.7 ll.24-26. This does not say what Plaintiffs say it says; it does not show that the word "amphetamine" is being used as an abbreviation for d-amphetamine. The paragraph just preceding these sentences defines "amphetamine" as including a very long list of names of compounds. '031 patent, col.6 l.46-col.7 l.2. This example supports Defendants' view that the patentees understood "amphetamine" to be a broad genus of compounds.

Plaintiffs are left to rely on the extrinsic evidence provided by their expert, Dr. Sawchuk. This Court does not find Dr. Sawchuk's opinion to be sufficient to override the express definition of "amphetamine" in the patent specifications. Defendants' proposed construction fits the express definition, and this Court adopts Defendants' proposed construction of "amphetamine:" the genus of amphetamines.

D. Terms 74 and 105, concerning release of amphetamine

Terms 74 and 105 overlap. Term 74 is the phrase, "limited release of amphetamine," which appears in claim 18 of the '735 patent. Term 105 is the phrase, "release of amphetamine as an active from said prodrug," which appears in claims 1 and 18 of the '735 patent. Plaintiffs assert that at issue is the question of whether "limited" here refers to the rate or to the extent of the release of the drug, contending that the limitation is one of rate of release, rather than extent of release. Yet that dispute concerns only term 74, which uses the word "limited," not term 105, which does not.

Defendants, in their opening brief, argue that "limited release" means "less than all is released," but support this with only the argument that Plaintiffs' construction is indefinite. Defendants' responsive brief makes some criticisms of Plaintiffs' proposed construction, but offers no support for Defendants' proposed construction.

Plaintiffs, on the other hand, contend that the intrinsic evidence supports their position as to term 74. The problem, however, is that the specification suggests that "limited release" involves limitations both as to rate and as to extent:

> Compounds, compositions and methods of the invention provide reduced potential for overdose, reduced potential for abuse or addiction, and/or improve amphetamine's characteristics with regard to high toxicities or suboptimal release profiles. Without wishing to be limited to the following theory, we believe that overdose protection results from a natural gating mechanism at the site of hydrolysis that limits the release of the active amphetamine from the prodrug at greater than therapeutically prescribed amounts. Therefore, abuse resistance is provided by limiting the "rush" or "high" available from the active amphetamine released by the prodrug and limiting the effectiveness of alternative routes of administration.

'735 patent, col.9 ll.3-15. This speaks directly to the question of what the patentees thought

about the limited release characteristics of the invented compounds: the release is limited physiologically by a natural gating mechanism. This clearly supports the understanding that the gating mechanism limits the rate at which the active ingredient is released. The idea of limiting the "rush" clearly invokes the concept of limiting the rate of release.

At the same time, the specification also supports the idea that there are limitations on the extent of release as well:

> In another embodiment, the covalent attachment of a chemical moiety substantially decreases the potential for overdose by decreasing the toxicity of amphetamine at doses above those considered therapeutic, while maintaining its pharmaceutical activity within a normal dose range. . . . At higher doses partial or complete saturation of processes responsible for amphetamine release may be reached thus diminishing or eliminating the release of harmful levels of active amphetamine.

Id. at col.4 l.64-col.5 l.8. This clearly expresses a limit on levels of amphetamine and, to eliminate the release of harmful levels of amphetamine, there must be a limit on the amount released.

This Court is not persuaded that either side's proposed narrowing construction of "limited release" is entirely correct. Neither party has convinced this Court that the meaning of "limited release" should be constrained to either "limited rate of release" or "limited extent of release." In claim construction, the Federal Circuit gives claim language the broadest reasonable construction, in light of the specification. Phillips, 415 F.3d at 1316. Neither party has proposed a construction which gives "limited release" its broadest reasonable construction, in light of the specification. Rather, the broadest reasonable construction of "limited release" is "release that is limited in terms of rate and/or extent."

As to term 105, which does not appear to involve the concept of a limitation on release,

the parties have not briefed this dispute sufficiently for the Court to ascertain it or resolve it.

E. Term 31: "and having an amphetamine base amount"

Term 31, "and having an amphetamine base amount," appears in many claims in six of the patents at issue. Plaintiffs contend that the base amount refers to the d-amphetamine component of LDX. Defendants contend that this means that the composition includes, in addition to LDX, and apart from it, some other amount of amphetamine base.

Defendants' position does not fit the plain language of the claims. For example, claim 1 of the '030 patent is: "A composition comprising an amount of from 25 to 75 mg of L-lysine-d-amphetamine or a salt thereof and having an amphetamine base amount of from 7.37 to 22.1 mg of said amphetamine, said L-lysine-d-amphetamine or a salt thereof providing a mean AUC . . ." There is no ambiguity here: the claim clearly states that the composition has a specific amount of LDX and a specific amount of "an amphetamine base amount . . . *of said amphetamine*." There is no way to make sense of this if the Court adopts Defendants' proposed construction. The amphetamine base amount is unambiguously some component of the "said amphetamine," as Plaintiffs contend. Defendants' proposed construction can only make sense if "of said amphetamine" is ignored.

Claim 1 of the '467 patent, claim 1 of the '619 patent, and claim 1 of the '305 patent have the same structure as claim 1 in the '030 patent: they specify an amount of LDX, followed by a clause which begins with "and having an amphetamine base amount," leading up to, "of said amphetamine."

Defendants' argument is that Plaintiffs' construction makes certain claims chemically impossible, and yet provides no expert support for this argument. This Court concludes that the

plain language of the claims demonstrates that "and having an amphetamine base amount" means "which contains an amphetamine base amount." As an example, claim 1 of the '030 patent reads: "A composition comprising an amount of from 25 to 75 mg of L-lysine-d-amphetamine or a salt thereof and having an amphetamine base amount of from 7.37 to 22.1 mg of said amphetamine, said L-lysine-d-amphetamine or a salt thereof providing a mean AUC . . ." Applying this construction, this claim would be understood to mean, "A composition comprising an amount of from 25 to 75 mg of L-lysine-d-amphetamine or a salt thereof which contains an amphetamine base amount of from 7.37 to 22.1 mg of said amphetamine, said L-lysine-d-amphetamine or a salt thereof providing a mean AUC . . ."

F. Terms 2, 3, and 3a: various milligrams

Plaintiffs attempt to persuade this Court that there is a genuine dispute over the meaning of the claim terms "25 mg," "25 to 75 mg," and "7.37 to 22.1 mg." Plaintiffs contend that, through claim construction, this Court should expand the ordinary meaning of these terms to incorporate a range of 85%-115% around the specific numerical values. Defendants contend that no construction is needed. This Court agrees with Defendants and finds that these terms are unambiguous and have their ordinary meaning. Plaintiffs seek to expand the scope of the claim beyond the bounds set by the plain claim language.

G. Term 110: "steady-state serum release curve"

Term 110, "steady-state serum release curve," appears in claim 11 of the '735 patent as well as claims 1, 17, 33, and 49 of the '936 patent. For example, this is claim 11 of the '735 patent:

The pharmaceutical composition of claim 1, wherein said

> L-lysine-d-amphetamine or pharmaceutically acceptable salt thereof is in an amount sufficient to maintain a steady-state serum release curve of amphetamine which provides a therapeutically effective bioavailability of amphetamine but prevents spiking or increased blood serum concentrations compared to unbound amphetamine.

The claim construction dispute between the parties centers on the time frame for the release curve: is it a single dose, or multiple doses? Defendants contend that a "steady-state serum release curve" is found when a serum level known as C_{min} remains equivalent during consecutive dosing periods. Plaintiffs contend that a "steady-state serum release curve" is found when serum levels from a single dose show a relatively constant and prolonged rate of appearance.[7]

Defendants cite one piece of intrinsic evidence. In the specification of the '936 patent, example 32 describes a study in which subjects were given once-daily doses of LDX on 7 consecutive days, and serum levels of d-amphetamine were measured at various points. The specification states: "By dose 5, d-amphetamine reached steady state." '936 patent, col.57 l.52. Defendants do not explain how this example supports their position, nor is it clear from the text of the patent. Example 32 shows no analysis of C_{min} levels, nor does it contain discussion of whether such levels remain equivalent during consecutive dosing periods. Nor do Defendants offer any expert opinion to help support their understanding of example 32; nor do their briefs give any discussion or explanation of example 32. The Court is left with only their conclusory assertion that this use of the phrase "steady state" in the specification supports their construction of "steady-state serum release curve."

Defendants offer three pieces of extrinsic evidence: 1) an FDA publication,

---

[7] Plaintiffs attempt to limit "steady-state serum release curve" to d-amphetamine. Plaintiffs have shown no basis for limiting this claim term to d-amphetamine, and this Court rejects that aspect of their proposed construction.

"Bioequivalence Guidance," which generally uses the phrase "steady state" in relation to multiple-dose studies;[8] 2) a dictionary definition of "steady state;" and 3) deposition testimony from Plaintiffs' expert, Dr. Sawchuk, about "steady state." The FDA publication colorably supports Defendants' construction, while the dictionary definition essentially says that a steady state is a condition of negligible change, which sheds no helpful light on this question.

As to the Sawchuk deposition testimony, Defendants point to two sections. The first deals with "steady state" pharmacokinetics generally and confirms that one can use "steady state" in the multiple-dose context, as Defendants contend, but Dr. Sawchuk states that that phrase's use is not limited to that context. (Devine Dec. Ex. 18 at 109:25-112:12.) In the second section, Dr. Sawchuk is asked about example 32 of the '936 patent and, while he agrees that the example uses the phrase "steady state," he states: "this doesn't address the steady state serum release curve." (Id. at 299:23-24.) If this isn't clear enough, with further questioning, Dr. Sawchuk explains that "steady state" in example 32 is used in a different context, and says, "it is referring to something other than release." (Id. at 300:16-17.) Rather than supporting Defendants' position, Dr. Sawchuk's deposition testimony supports the contrary proposition that example 32 is not informative about serum release curves.

Plaintiffs support their construction primarily with two pieces of intrinsic evidence. First, Plaintiffs point to this statement in the specification of the '735 patent:

> Another embodiment provides a method of reducing bioavailability of amphetamine comprising providing amphetamine covalently bound to a chemical moiety, wherein the bound amphetamine maintains a steady-state serum release

[8] As Defendants contend, the document states: "Generally, three successive CMIN values should be provided to verify that steady state conditions have been achieved." (Devine Dec. Ex. 12 at VYVANSE_JDG_00050061.)

> curve which provides a therapeutically effective bioavailability but prevents spiking or increased blood serum concentrations compared to unbound amphetamine when given at doses exceeding those within the therapeutic range for the unbound amphetamine.

'735 patent, col.18 ll.6-14.[9] Plaintiffs also point to this paragraph in the specification of the '936 patent:

> Preferably, the amphetamine prodrug provides a serum release curve that does not increase above amphetamine's toxicity level when administered at higher than therapeutic doses. The amphetamine prodrug may exhibit a reduced rate of amphetamine absorption and/or an increased rate of clearance compared to the free amphetamine. The amphetamine prodrug may also exhibit a steady-state serum release curve. Preferably, the amphetamine prodrug provides bioavailability but prevents C_{max} spiking or increased blood serum concentrations.

'936 patent, col.11 ll.17-26.

This intrinsic evidence provides a key clue to the meaning of "steady-state serum release curve." In this evidence, and in many other places in the patents at issue, the patentees contrast "steady-state serum release curve" with "spiking," as in claim 1 of the '936 patent: "A method, in a subject in need thereof, of providing an amphetamine in a steady-state serum release curve without spiking blood serum concentrations . . ." It is clear that "spiking" refers to the characteristic of graphs of blood serum amphetamine level across time to show a spike – a sharp increase and then decrease in serum levels, as the body responds to a single dose. It is worth noting that Defendants, after first arguing that the claim term "spiking" is insolubly ambiguous, offer an alternative construction involving "a pharmacokinetic profile where the slope of the curve leading to C_{max} is steep." (Defs.' Br. 28.) This implicitly acknowledges that the curve of interest, when discussing spiking, is that of blood level across time for a single dose.

---

[9] The '735 specification contains similar statements about other embodiments. '735 patent, col.12 ll.36-45; col.12 ll.52-58; and col.18 ll.22-30.

The patents as a whole make clear that one of the main advantages of the amphetamine prodrug that the inventors invented was that, when given as a single dose, the prodrug releases amphetamine into the human body in a more constant and even manner than unmodified amphetamines do, which tend to show spiking patterns in their release profile and which cause a "rush" because of this. The "steady-state serum release curve" manifests this key aspect of the inventions. Moreover, there is nothing in these patents that suggests that spiking is a phenomenon related to multiple doses.

The evidence offered by the parties supports Plaintiffs' construction of "steady-state serum release curve," except insofar as Plaintiffs limit this term to d-amphetamine. Thus this Court construes this term to mean a "serum release curve which shows a relatively constant and prolonged rate of appearance of the active."

H. Terms 96, 103, 104, and 109: "spiking"

The main dispute over "spiking" is whether, as Defendants claim, the term is "insolubly ambiguous—that it fails to provide sufficient clarity delineating the bounds of the claim to one skilled in the art." Biosig Instruments, Inc. v. Nautilus, Inc., 715 F.3d 891 (Fed. Cir. 2013).

At the outset, the Court notes that it is not presently entertaining an invalidity challenge, but doing claim construction. The issue of whether certain claims are invalid for indefiniteness, pursuant to paragraph 2 of § 112, is a matter for another day.

When comparing Plaintiffs' proposed construction to Defendants' alternative proposed construction, there does not appear to be any substantial dispute between the parties. Defendants propose that "spiking" is characterized by "the slope of the curve leading to C_{max} is steep," while

Plaintiffs propose that it is characterized by rapidly increasing blood serum concentrations.[10] With the exception of Defendants' reference to C_{max}, if there is a meaningful difference here, the parties have failed to point it out.

As to C_{max}, the only intrinsic evidence Defendants cite in support is this statement in the specification of the '936 patent: "Preferably, the amphetamine prodrug provides bioavailability but prevents C_{max} spiking or increased blood serum concentrations." '936 patent, col.11 ll.24-26. Plaintiffs argue that a spike could appear in a serum concentration curve that does not immediately approach C_{max}, and this makes sense. The '936 and '735 patents sometimes speak of spiking in the context of C_{max}, and sometimes without reference to C_{max}. The claims themselves do not connect spiking to C_{max}. This Court sees no basis to conclude that the patentees understood "spiking" as restricted to curves leading immediately to C_{max}.

Although the parties' proposed constructions differ in the words employed, both define spiking only in terms of the upsurge that begins the spike, with no mention of the remainder of the spike. Because the parties appear to have agreed on this approach to defining "spiking," this Court will adopt it. As stated, with the exception of the reference to C_{max}, and the limitation to d-amphetamine, the parties' proposed constructions do not appear to differ materially, and this Court construes "spiking" as "rapidly increasing blood serum concentrations."

I. Term 25a: "bioavailability" and "alternate routes of administration"

Term 25a concerns the term, "limited bioavailability of amphetamine when administered through alternative routes of administration." The parties identify two areas of dispute with

[10] Again, Plaintiffs seek to limit this term to d-amphetamine and, again, this Court finds no basis to limit it so.

regard to this term: 1) the issue of whether "bioavailability" includes rate of absorption; and 2) the meaning of "alternative routes of administration."

As to the first question, the parties agree that, in the context of the '561 and '936 patents, bioavailability "includes extent but not rate of absorption." (Pls.' Br. 22 n.8.) The parties dispute the meaning of "bioavailability" only in the '735 patent: Plaintiffs contend that, in that patent only, "bioavailability" concerns both the extent and rate of absorption, while Defendants contend that it concerns only the extent of absorption. As Defendants note, it is striking that Plaintiffs propose differing constructions of "bioavailability" for the '735, '561, and '936 patents. It is true "that the same claim term can have different constructions depending upon the context of how the term is used within the claims and specification." Aventis, 715 F.3d at 1374. The challenge for Plaintiffs is to point to intrinsic evidence of differing contexts for differing constructions.

Plaintiffs support their position with one piece of intrinsic evidence concerning Table 46 in the '735 patent. Plaintiffs argue that Table 46 contains data concerning bioavailability, and gives statistics both for AUC and C_{max}.[11] What Plaintiffs do not demonstrate with intrinsic evidence, however, is that the patentees viewed C_{max} as a measure of rate of absorption. Lacking intrinsic evidence that sheds light on this question, this Court turns to the extrinsic evidence, which consists of the statements of Plaintiffs' expert, Dr. Sawchuk, whose declaration states:

> AUC, C_{max}, and T_{max} characterize the rate and extent of absorption of a drug. A metric or parameter for evaluating the extent of absorption of a drug is the area under the curve or "AUC." This is the area under the plasma or serum concentration-time curve that is a measure of the amount of drug that is absorbed

[11] It does seem clear that, in the specification of the '735 patent, the patentees offered both AUC and C_{max} statistics to show bioavailability. See, e.g., '735 patent, col.52 l.47; col.52 l.64.

> following administration of a drug or a prodrug. The metric or parameter "C_{max}" refers to the maximum concentration and is a measure of the rate and extent of absorption of a drug. The metric or parameter "T_{max}" refers to the time to reach the C_{max} and is a measure of the rate of drug absorption.

(Fleming Dec. Ex. 72 ¶ 50.) Plaintiffs point to Dr. Sawchuk's statement that C_{max} is a measure of both rate and extent of absorption, but the Court finds this unpersuasive. Dr. Sawchuk stated that C_{max} means "maximum concentration" and that T_{max} is the time to reach that maximum. Rate is, by its ordinary definition, a relative measure, a ratio of one thing to another. Maximum concentration is not a relative measure. In particular, it does not appear to be a measure of absorption over time, as T_{max} is defined as time to reach maximum concentration. It is not clear that Table 46 shows that, in the '735 patent, the patentees intended "bioavailability" to mean both extent and rate of absorption.

In his declaration, Dr. Sawchuk offers a quote from the prosecution history that fails to support his position:

> In [a] single-dose, three-way crossover study, 12 adult stimulant abusers were intravenously administered (i) 25 or 50 mg L-lysine-d-amphetamine dimesylate, (ii) immediate release d-amphetamine sulfate (10 or 20 mg), or (iii) placebo. . . .
>
> The mean T_{max} of d-amphetamine following administration of L-lysine-d-amphetamine dimesylate was significantly longer than that of d-amphetamine sulfate (2.5 vs. 0.8 hours). Furthermore, the mean maximum concentration of d-amphetamine for 50 mg Llysine-d-amphetamine dimesylate (equivalent to 20 mg damphetamine base) was less than half that of 20 mg d-amphetamine sulfate . . . Despite the longer time to C_{max}, the mean AUC for L-lysine-d-amphetamine dimesylate was similar to that of d-amphetamine. The longer time to C_{max} may contribute to a decreased likelihood of abuse. Volkow et al. (J. Attention Disorders, 6 (Suppl. 1):S-31-S-43, S-33) . . . ("the rate at which a stimulant drug enters the brain is essential for enabling its reinforcing effect (faster delivery of drugs into the brain is associated with greater reinforcing effects)") . . . .

(Fleming Dec. Ex. 72 ¶ 217, quoting Ex. 34, '561 patent file history at SHRVYV0032467). It is

clear that, in this quote, C_{max} measures the maximum concentration of the drug, and T_{max} measures the time to reach that concentration. The word "rate" is used in a context which indicates that it refers to the measure of maximum concentration relative to time. This quote does not suggest that C_{max} is a measure of rate, independent of T_{max}. Rather, it appears that the rate at which a drug enters the brain is reflected in T_{max} and C_{max} together – C_{max} in relation to T_{max}. The fact that Table 46 in the '735 patent concerns bioavailability and gives C_{max} statistics does not persuade this Court that "bioavailability" in the '735 patent has a different meaning from that in the '561 and '936 patents.

The aspect of Plaintiffs' position here that is most troubling is the idea that the patentees used "bioavailability" to mean one thing in two patents, but something different in a third. Their argument appears to be based on the contention that the context of the use of "bioavailability" varies its meaning. There is, however, nothing in the context of the usage in the '735 patent that suggests that its meaning is different from that in the '561 and '936 patents.

Plaintiffs point instead to a special definition of "bioavailability" in the specification of another of the patents at issue, but not at issue with regard to this question of claim construction. The specification of the '253 patent states: "The term 'bioavailability' refers to the rate and extent to which a drug is absorbed." '253 patent, col.19 ll.33-34. This, however, works against Plaintiffs' position, since it shows that the patentees clearly set forth a special definition of "bioavailability" in the '253 patent, but did not do so in the '735 patent. The Court sees this as important evidence that the patentees did not intend to clearly give "bioavailability" a special definition in the '735 patent.

Plaintiffs have not persuaded this Court that, in the '735 patent, the patentees used a

definition of "bioavailability" that differs from its meaning in the '561 and '936 patents, and that differs from the definition that the parties have otherwise agreed to, the extent of absorption. This Court concludes that "bioavailability" refers only to the extent of absorption in the '735, '561, and '936 patents.

As to the phrase, "alternative routes of administration," Plaintiffs propose that this is limited to administration through intravenous, intranasal, or inhalation routes, while Defendants propose a broader definition: administration other than solely by mouth. Plaintiffs contend that Defendants' construction is too broad, since there are non-oral ways to administer the medication that are not often employed in illicit use, such as topical or optical use, or use as a suppository. Defendants contend that Plaintiffs' construction is too narrow.

Defendants do not offer a cogent argument to support their broad construction beyond noting that Plaintiffs seek to limit the term to the examples given in the specification. Indeed, Plaintiffs point to this statement in the specification of the '735 patent: " The compositions are also resistant to abuse by parenteral routes of administration, such as intravenous 'shooting', intranasal 'snorting', or inhalation 'smoking', that are often employed in illicit use." '735 patent, col.1 ll.33-36.

It is not clear to this Court that this dispute is of any significance. Nonetheless, Plaintiffs' construction appears somewhat too narrow, and Defendants' is somewhat too broad. It is abundantly clear from the specifications of all the patents that one of the chief benefits of the invented compounds is that they are less likely to be abused by drug abusers, and that these compounds are less likely to provide a "rush" when administered in the ways most often

employed by drug abusers.[12] "Alternative routes of administration" should be given the broadest meaning consistent with this idea. It would be unduly narrow to restrict it only to those routes of administration given as examples in the specification, but unduly broad to extend it to all non-oral routes, even those that are not often employed in illicit use. This Court concludes that "alternative routes of administration" should be construed to mean "parenteral routes of administration often employed in illicit use."

J. Terms 26 and 59: "C_{max} which results in euphoria"

Terms 26 and 59 involve the phrase, "C_{max} which results in euphoria," which appears in claim 10 of the '735 patent and claim 11 of the '486 patent. Plaintiffs contend that this phrase needs no construction, and that it carries its ordinary meaning, whereas Defendants contend that the phrase is insolubly ambiguous and therefore indefinite. As previously discussed, this Court will not address validity challenges, based on indefiniteness or any other argument, at this juncture.

As also previously discussed, Defendants' indefiniteness argument misapprehends Federal Circuit law. Defendants argue that the patent provides no information about what C_{max} level results in euphoria. Defendants have given this Court no basis to conclude that this could not be readily discovered by the skilled artisan. "[O]bjections relating to the mere fact that there may be some need for experimentation to determine the scope of the claims carry little weight." Biosig, 715 F.3d at 902.

---

[12] Defendants argue: "The entire purpose of the '735 patent is to distinguish between delivering the lisdexamphetamine enterally versus non-enterally." As Plaintiffs point out, this is wrong, and one need only look at the title of the '735 patent to see what the patentees understood the purpose of the invention to be: "Abuse Resistant Lysine Amphetamine Compounds."

This Court agrees with Plaintiffs that the term, "C_{max} which results in euphoria," has its ordinary meaning.

K. Term 92: "a patient intent on taking an amphetamine or a salt thereof inconsistent with the manufacturer's instructions"

Term 92, "a patient intent on taking an amphetamine or a salt thereof inconsistent with the manufacturer's instructions," appears in independent claims 20 and 39 of the '788 patent. As an example, claim 20 states:

> A method of treating attention deficit hyperactivity disorder, in a patient intent on taking an amphetamine or a salt thereof inconsistent with the manufacturer's instructions, said method comprising supplying the amphetamine in the form of L-lysine-d-amphetamine or a salt thereof.

The parties' briefing does not show any true dispute over the meaning of any of the words in term 92. Although the parties debate how best to rephrase this term, the parties point out no genuine question about the meaning of any of the key words here: "patient," "intent," "manufacturer," or "instructions." The parties agree that this phrase is understood in the context of this statement in the specification:

> Thus, the amphetamine prodrug may prevent and/or reduce the potential of abuse and/or overdose when the amphetamine prodrug is used in a manner inconsistent with the manufacturer's instructions, e.g., consuming the amphetamine prodrug at a higher than therapeutic dose or via a non-oral route of administration.

'788 patent, col.10 ll.20-25. Defendants propose a construction which adds requirements for a diagnosis and for patient knowledge of the product label, yet point to no place in the patent in which the patentees indicated such limitations. This Court finds no basis for Defendants' additional limitations. The patent does not require the patient to have any knowledge of the manufacturer's instructions, nor does it require a preceding diagnostic process.

The Court adopts Plaintiffs' proposed construction of "a patient intent on taking an amphetamine or a salt thereof inconsistent with the manufacturer's instructions:" "a patient intent on taking an amphetamine at a higher-than-therapeutic dose or via a non-oral route of administration that is often employed in illicit use."

L. Terms 23 and 38: "administering" and "orally administered"

Term 23, "administering," and term 38, "orally administered," appear in numerous claims in numerous patents. Plaintiffs contend that no construction is needed and that these terms have their ordinary meanings. Defendants contend that the terms should be construed to mean "physically delivering into the body of the patient." Plaintiffs argue that there is no basis to narrow the term so, which is correct – though it might be more correct to say that Defendants seek to distort the term rather than narrow it. There is certainly no basis to conclude that the patentees invented a treatment in which physicians physically delivered the medication into the body of the patient. Were this a medication given intravenously, there might be a case for this, but the patents are quite clear that the medication is an ordinary pill, administered orally, just like an aspirin might be given.

Defendants' argument goes as follows. Defendants point to claim 1 of the '936 patent as an example:

> A method, in a subject in need thereof, of providing an amphetamine in a steady-state serum release curve without spiking blood serum concentrations, said method comprising administering to said subject L-lysine-d-amphetamine or a salt thereof, whereby said L-lysine-d-amphetamine or a salt thereof maintains a steady-state serum release curve which provides therapeutically effective bioavailability of said amphetamine, but without spiking blood serum concentrations of said amphetamine when compared to the administration to said subject of the same amount of said amphetamine in the form of D-amphetamine.

Defendants argue: "A patient's ADHD cannot be treated and the patient cannot have drug-in-blood levels unless 'administering' means physically delivering the drug into the body of the subject." (Defs. Br. 33.) This argument overlooks the well-settled function of "comprising" in patent law: "'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997). Because claim 1 of the '936 patent uses the transitional phrase, "comprising," other elements may be added in construing the claim, and it is these other elements that fill in the gap between administering the compound to the patient and its release into the patient's bloodstream. There is no need to expand the meaning of "administering" to fill that gap. Nor does Defendants' citation to the deposition testimony of Plaintiffs' expert show otherwise – Dr. Sawchuk is simply filling the gap in line with common sense and the specification, not giving an expert opinion on the meaning of "administering." (Devine Dec. Ex. 18 151:13-152:2.)

There is no dispute that the patents envision a method of treatment in which the pharmaceutical is orally ingested by the patient. The problem with Defendants' proposed construction is the implication that the treating professional must physically deliver the pharmaceutical into the patient's mouth. Contrary to Defendants' position, the patents do not appear to envision a method of treatment in which the treating professional physically delivers the invented compound into the body of the patient. Consider claim 30 of the '788 patent: "A method of decreasing abuse of amphetamines or salts thereof, in a subject in need thereof, said method comprising administering said amphetamine to said subject in the form of L-lysine-d-amphetamine or a salt thereof." If "administering" means, as Defendants propose,

physically delivering into the body of the patient, this renders meaningless the phrase, "a method of decreasing abuse." This phrase is meaningful because of the fact that the treating professional does not deliver the medication into the body of the patient but, rather, the patient has the choice to abuse the medication by taking it intranasally or intravenously – options that could not exist if the physician placed the pill on the patient's tongue.

This Court agrees with Plaintiffs that "administering" and "orally administered" have their ordinary meaning.

M. Term 24a: "adult subject"

Plaintiffs propose that "adult subject" has its ordinary meaning, one who is physically mature, while Defendants contend that it refers to a person of age 18 or older. This Court finds no basis in the patent to construe "adult" as based on the legal standard of majority. "Adult subject" has its ordinary meaning, as Plaintiffs propose.

N. Term 67: "in a subject in need thereof"

Term 67, "in a subject in need thereof," appears in numerous claims in numerous patents. Defendants contend that the term has its ordinary meaning and that no construction is needed. Plaintiffs contend, in brief, that it should be construed as, "in a subject with a recognized and appreciated need for. . . ." Plaintiffs ground their argument on the fact that, in one case, Jansen v. Rexall Sundown, Inc., 342 F.3d 1329, 1334 (Fed. Cir. 2003), the Federal Circuit approved a similar construction. In the absence of any other basis for Plaintiffs' proposed construction, that alone is not sufficient to persuade this Court that there is any genuine and material question about the meaning of the term "in a subject in need thereof" such that construction is needed.

O. Are the "wherein" and "whereby" clauses claim limitations?

Clauses with "whereby" or "wherein" appear in claims 1, 17, 33 and 49 in the '936 patent, claims 1, 2, and 16 through 18 in the '735 patent, and claims 5 through 9 of the '561 patent.[13] The parties both argue in the aggregate about whether these clauses should be treated as claim limitations.

Defendants contend that the sixteen clauses are "merely the natural results of positively recited claim limitations" and, as such, are not claim limitations under Federal Circuit law. (Defs.' Br. 14.) Defendants point to Minton v. NASD, 336 F.3d 1373, 1381 (Fed. Cir. 2003), in which the Federal Circuit held: "A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited."

The problem for Defendants is that Minton does not state any bright line rule applicable to the construction of whereby clauses. In Hoffer v. Microsoft Corp., 405 F.3d 1326, 1329 (Fed. Cir. 2005), the Federal Circuit, after acknowledging the holding of Minton, stated: "However, when the 'whereby' clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention."

Moreover, Defendants rely on a bright line rule which their cited cases do not support: a "whereby" clause stating inherent characteristics of the invention does not state a claim limitation. That is not the holding of Minton. Defendants also cite Texas Instruments v. United States ITC, 988 F.2d 1165, 1172 (Fed. Cir. 1993) and In re Mason, 244 F.2d 733, 735 (C.C.P.A. 1957), but those cases do not say anything on this issue which differs from Hoffer: the key

[13] There are sixteen clauses in fourteen claims; two of the claims have two such clauses each.

question is whether or not the clause states a condition material to patentability.

Under Hoffer, this Court must examine each "whereby" clause and determine whether it states a condition that is material to patentability. It cannot be decided *en masse*, as Defendants propose. These are issues for another day – perhaps when particular claims are at issue in an infringement or invalidity inquiry.

In conclusion, as to Civil Action No. 11-3781, this Court construes "L-lysine-d-amphetamine" to not include protected forms, "L-lysine-d-amphetamine dimesylate" as "L-lysine-d-amphetamine dimesylate (that may have a water content)," "X-ray powder diffraction pattern substantially as shown in FIG. 77" as "X-ray powder diffraction pattern approximately as shown in FIG. 77," "amphetamine" as "the genus of amphetamines," "limited release of amphetamine" as "release that is limited in terms of rate and/or extent," the milligram dosage terms as having their ordinary meaning, "and having an amphetamine base amount" as "which contains an amphetamine base amount," "steady-state serum release curve" as "serum release curve which shows a relatively constant and prolonged rate of appearance of the active," "spiking" as "rapidly increasing blood serum concentrations," "bioavailability" as referring only to the extent of absorption in the '735, '561, and '936 patents, "alternative routes of administration" as "parenteral routes of administration often employed in illicit use," "C_{max} which results in euphoria" as having its ordinary meaning, "a patient intent on taking an amphetamine or a salt thereof inconsistent with the manufacturer's instructions" as "a patient intent on taking an amphetamine at a higher-than-therapeutic dose or via a non-oral route of administration that is often employed in illicit use," "administering" and "orally administered" as having their ordinary meanings, and "adult subject" as having its ordinary meaning. The Court otherwise is either

unable to ascertain disputes amenable to claim construction, or rejects the parties' arguments, as explained above.

As to Civil Action No. 12-83, because Defendants Johnson Matthey Inc. and Johnson Matthey Pharmaceutical Materials have not opposed Plaintiffs' application for claim construction, in that case only, Plaintiffs' application for claim construction is granted in its entirety.

SO ORDERED.

s/Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: August 8, 2013